Preventing Attacks Through Biodefense & Preparedness

Bioterrorism is among the most serious threats to homeland security because of its potential to harm millions and spread massive terror. The Administration has not responded to this threat as aggressively or as comprehensively as is needed, leaving foreign and domestic stores of deadly pathogens unsecured, insufficiently addressing a severely neglected and overtaxed health infrastructure, and providing an incomplete plan to develop new vaccines and treatments to neutralize this threat. A comprehensive approach to bioterrorism requires concerted effort in three areas: prevention, including developing new and strengthening existing programs to secure pathogen stocks around the world; preparedness, including completing a comprehensive biodefense plan, strengthening and better targeting federal public health funding; and protection, developing the ability defend our population through deploying the drugs, vaccines, and diagnostics required to combat infection and illness.

Well before 2001, public health experts warned that biological weapons could serve as the ideal weapon of terror, easily spreading fear and confusion, capable of causing mass casualties, and difficult to trace.[1] The anthrax attacks of October-November 2001 provided a startling demonstration of the ability of bioterrorism to murder, spread fear, and paralyze infrastructure. U.S. officials believe that al Qaeda is pursuing sophisticated biological weapons.[2] A United Nations panel recently declared it is "just a matter of time" before al Qaeda attempts a biological or chemical attack.[3] Yet, despite a flurry of initiatives over the past two years, serious gaps remain in the endeavor to prevent, deter, and respond to bioterrorism. The Administration has not moved as quickly or aggressively as is required to address this evolving threat, leaving the nation without an effective response.

---

[1] (a) D.A. Henderson, "Bioterrorism as a Public Health Threat," *Emerging Infectious Disease*, 4, no.3 (July-September 1998): 488-492; (b) John Schwartz and Michael Osterholm, *Living Terrors: What America Needs to Know to Survive the Coming Bioterrorist Catastrophe*, (New York: Dell Publishing, 2000); (c) Institute of Medicine, *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response*, (Washington, D.C.: National Academy Press, 1999).

[2] (a) Central Intelligence Agency, *Terrorist CBRN: Materials and Effects*, http://www.cia.gov/cia/reports/terrorist_cbrn/terrorist_CBRN.htm, visited January 22, 2004; (b) Department of Homeland Security, "Maintaining Awareness Regarding Al-Qaeda's Potential Threats to Homeland," press release, September 4, 2003, http://www.dhs.gov/dhspublic/display?content=1442; (c) Matt Kelley, "Pentagon: Al Qaeda Pursuing Bioweapons," *Associated Press*, May 23, 2003.

[3] Vivienne Foley, "U. N. Details Al Qaeda Threat," CNN.com, November 20, 2003, http://www.cnn.com/2003/US/11/20/un.alqaeda/.

Preventing the Use of Biological Weapons

The best means for preventing bioterrorism is to keep dangerous biological materials out of the hands of terrorists. A top government priority should be to minimize the chance dangerous pathogens, such as anthrax, smallpox, or Ebola virus, being deployed against vulnerable populations. Stores of these pathogens, and the expertise to use them as weapons, remain in many sites in the former Soviet Union, in research laboratories throughout the world,[4] and, increasingly, in research facilities in the United States.[5]

SECURITY GAP: Biological Weapon Sites in the Former Soviet Union Remain Unsecured.

As discussed in a previous chapter, the legacy of Soviet weapons of mass destruction programs, including the largest and most intensive biological weapons program in history, have left dangerous materials and expertise susceptible to theft or appropriation by terrorist groups. Cooperative Threat Reduction programs with Russia and other former Soviet states, managed through several U.S. agencies, were established beginning in 1991 to deal with these threats. However, chronic underfunding and a lack of strong leadership and management have hindered the success of these efforts. Funding for Department of Defense (DOD) security improvements have remained flat at $55 million since fiscal year 2003.[6] Meanwhile, the General Accounting Office (GAO) has reported disarray in DOD efforts to secure former biological weapons sites.[7] After four years, DOD has made limited progress, with security projects underway at only four of 49 known biological sites and with only two sites secured against external threats.[8] Deficiencies include:

- Lack of assessments of the number, location, pathogen inventory, and current security status of bioweapon sites;
- A lack of a plan or timeframe for completing security upgrades;
- Failure to address "insider" threats that may lead to theft of agents.[9]

The Russian government has also been uncooperative in the effort to secure some former bioweapon sites. The Ministries of Defense and Agriculture have blocked access to certain facilities, while the Russian government has rejected the establishment of interagency agreements concerning implementation of security measures.[10]

GAO has also found that the International Science Centers program, an effort managed by the Department of State and intended to occupy former Soviet weapons scientists in peaceful

---

[4] Michael Barletta, Amy Sands, and Jonathan Tucker, "Keeping Track of Anthrax," *Bulletin of the Atomic Scientists* 58, no. 3 (May/June 2002): 57.
[5] Brad Knickerbocker, "Concern Over Spread of Biodefense Labs," *Christian Science Monitor*, September 25, 2003, 2.
[6] Nuclear Threat Initiative, *Controlling Nuclear Warheads and Materials: Threat Reduction Budgets*, http://www.nti.org/e_research/cnwm/charts/cnm_funding_interactive.asp, visited February 13, 2004.
[7] U.S. General Accounting Office, *Weapons of Mass Destruction*: *Additional Russian Cooperation Needed to Facilitate U.S. Efforts to Improve Security at Russian Sites*, GAO-03-482, (Washington, D.C.: GAO, March 2003).
[8] Ibid, 50.
[9] Ibid, 44-49.
[10] Ibid, 53-56.

research work.[11] Of the 6,500 former biological and nuclear weapons scientists, 75 percent spent less than a third of their time on approved research projects, with no accounting for their other activities.[12] Meanwhile, the program has been essentially flat-funded at approximately $50 million since fiscal year 2001.[13]

SECURITY RECOMMENDATION

To address these shortcomings, funding for nonproliferation programs targeted at the former Soviet Union should be strengthened. Current funding, at approximately $1 billion per year, is too low to secure or eliminate existing weapons of mass destruction, including biological weapons stockpiles, facilities, and capabilities. A tripling of current funding, to $30 billion over the next 10 years, is required to secure all weapons of mass destruction sources and keep them out of the hands of terrorists.[14] A portion of these increases should be directed to identifying and securing bioweapons facilities from insider and outsider threats, as well as better tracking bioscientists' activities. Russian obstructionism in the effort to secure potential biological weapons is not acceptable. The Administration needs to increase pressure on Russian officials to cooperate and resolve disagreements blocking the achievement of security. Obtaining this cooperation must be a high priority in our dealings with Russia.

SECURITY GAP: There Are No International, Standardized Security Guidelines for Pathogen Research Sites and Collections.

Today, no comprehensive, uniform, global standards for laboratory security exist on which individual states can base national legislation and regulatory regimes.[15] Instead, potential bioweapons agents are stored in collections and laboratories in numerous countries, under varying degrees of security, and are exchanged through poorly monitored "germ commerce."[16] As a result, terrorist organizations could exploit poorly protected facilities or research material exchange systems, gain access to toxins and pathogens, and then use the material for bioterrorism on U.S. soil. The Administration has suggested that the World Health Organization (WHO) should take the lead in developing and communicating voluntary guidelines, and then wait for every nation to adopt regulations to meet these guidelines.[17] However, WHO is a public health and scientific organization, and it is not well equipped to deal with what is fundamentally a security issue. Moreover, such a process is likely to be slow, and fails to incorporate

---

[11] GAO, *Weapons of Mass Destruction*: *State Department Oversight of Science Centers Program*, GAO-01-582, (Washington, D.C.: GAO, May 2001).
[12] Ibid, 18-19.
[13] Nuclear Threat Initiative, *Controlling Nuclear Warheads and Materials: Threat Reduction Budgets*, http://www.nti.org/e_research/cnwm/charts/cnm_funding_interactive.asp, visited February 13, 2004.
[14] U.S. Department of Energy, Secretary of Energy Advisory Board, *A Report Card on the Department of Energy's Nonproliferation Program's with Russia*, January 10, 2001.
[15] Jonathan B. Tucker, *Biosecurity: Limiting Terrorist Access to Deadly Pathogens*, Peaceworks No. 52 (Washington, D.C.: U.S. Institute of Peace, 2003).
[16] Jonathan B. Tucker, "In the Shadow of Anthrax: Strengthening the Biological Disarmament Regime" *The Nonproliferation Review*, (Spring 2002): 112; *see also* William J. Board, "Obtaining Anthrax Is Hard, But Not Impossible," *New York Times*, October 10, 2001, B12.
[17] Bureau of Arms Control, U.S. Department of State, *Security of Dangerous Pathogens and Toxins - Release from the August meeting of Experts to the Biological Weapons Convention*, August 25, 2003.

accountability, leaving a patchwork of inconsistently implemented and enforced regulations that could be exploited by terrorists.

SECURITY RECOMMENDATION

Having suffered from bioterrorism and as initiator of the world's largest biodefense research effort, the U.S. should provide leadership in the international arena to help secure dangerous agents that could be used as weapons in all countries. The Administration should reinvigorate multilateral negotiations towards developing effective and enforceable global controls on pathogen use, storage, and transfer.

SECURITY GAP: Efforts To Secure U.S. Pathogen Research Sites and Collections Have Been Inadequate.

In the U.S., stocks of dangerous pathogens, high-level laboratories to house them, and the number of people working with them are growing rapidly as efforts to improve the nation's biodefense expand. These reinvigorated efforts are essential to improving our biodefense, but they also bring more opportunities for the accidental or intentional escape of pathogens from legitimate facilities.[18]

Congress mandated an increase in the security of inventories, laboratories, and personnel in the Bioterrorism Preparedness Act of 2002, establishing the "select agent" regulatory programs at the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA).[19] However, effective implementation of these security requirements has lagged. According to GAO, CDC suffered from "significant management weaknesses" that undermined administration of a relatively small regulatory program initiated before September 11.[20] Now, in charge of the much more expansive, post 9/11 requirements, the CDC, traditionally reluctant to manage a regulatory program, continues to struggle. Along with the Federal Bureau of Investigation and the USDA, the agency still has not met a deadline, originally set for November 12, 2003, for certifying the security of laboratories that use deadly pathogens.[21] The certification process requires facilities possessing dangerous agents to register with the government, and for the completion of a security risk assessment, implementation measures to ensure security, and the conduct of background checks on personnel with access to the agents. Instead of ensuring this security, the Administration has issued "provisional" certificates, with no timeline for final approval.

In the past, security at many research facilities has been weak. A USDA audit of more than 100 laboratories conducting publicly funded experiments on hazardous biological agents illustrated a number of security shortcomings, including a lack of security cameras and appropriate locks on

---

[18] Eileen Choffness, "Bioweapons: New Labs, More Terror?" *Bulletin of the Atomic Scientists*, 58, no. 5 (September/October 2002): 28-32.
[19] Title II, *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, PL 107-188.
[20] GAO, *Homeland Security: CDC's Oversight of the Select Agent Program*, GAO-03-315R, (Washington, D.C.: GAO, November 2002).
[21] John Mintz, "U.S. Fails to Certify Many Labs that Use Pathogens," *The Washington Post*, November 12, 2003, A13.

doors and freezers, and poor or non-existent inventory records.[22] Even though the federal government has spent more than $3 billion in biodefense research and development over the last two years, verified safeguards at our own laboratories are woefully inadequate.

SECURITY RECOMMENDATION

The Administration should make it a high priority to fully implement the CDC and USDA select agent regulations mandated by Congress in order to secure pathogen stocks in this country. If these agencies do not take swift action, Congress should consider transferring responsibility for the "select agent" program to the Department of Homeland Security (DHS). While securing these laboratories must be done with appropriate balance so as to minimize the burden and uncertainty faced by researchers, our nation's domestic security demands action instead of indefinite delay. In forging the cooperation and consistency between two separate cabinet-level agencies necessary for successful implementation of these security requirements, stronger leadership from the Administration appears necessary.

Effective Bioterrorism Preparedness for America

Preventing terrorist access to pathogens will reduce the risk of bioterrorism, but it cannot eliminate it. The recent anthrax and ricin attacks demonstrated that criminals already possess the ability to manufacture bioweapons. While terrorists can most easily acquire pathogens from existing stocks, many dangerous microbes and toxins can be extracted from natural sources as well. Finally, and most disturbingly, the knowledge and skill to bioengineer new, dangerous strains of pathogens and types of poisons is growing. According to an expert CIA panel, rapid advances in biotechnology are making possible the creation of biological agents that "could be worse than any disease know to man."[23] In the face of this evolving threat, effective bioterrorism preparedness is essential for homeland security, as it will save lives, calm the public, and, when achieved and demonstrated, deter bioterrorists.

SECURITY GAP: There is No Coherent or Comprehensive Biodefense Preparedness and Response Strategy.

A clear, overarching strategy is needed for biodefense preparedness and response, with well-defined and measurable goals for preparedness that are based on recognized threats and vulnerabilities. Without one, federal efforts risk being at best inscrutable, duplicative and wasteful, and, at worst, dangerously fragmented and uncoordinated. Unfortunately, the Administration has still not developed a coherent plan for biodefense preparedness and response, nor has it articulated an integrated, comprehensive strategy for building our biodefense. Federal cabinet agencies with responsibilities for bioterrorism preparedness and response include the Department of Homeland Security, the Department of Justice, the Department of Energy, the Department of Defense, the Department of Health and Human Services, the Department of

---

[22] *Associated Press*, "Bioterror Concerns Raised at Universities," November 21, 2003.
[23] Office of Transnational Issues, Central Intelligence Agency, *The Darker Bioweapons Future*, OTI SF 2003-108, November 3, 2001, http://www.fas.org/irp/cia/product/bw1103.pdf.

Agriculture, and the Veterans Administration.[24] These agencies must work with each other and, in turn, must coordinate with a plethora of state, local, and private institutions to develop standards and procedures for a coordinated preparedness and response to health crises. While a national strategy specifically addressing bioterrorism issues, *the National Strategy to Combat Weapons of Mass Destruction*, was released in December 2002, it is vague and does not clearly identify federal agency roles and responsibilities.[25] While the Department of Health and Human Services (HHS) is required by law to complete a national preparedness plan for public health emergencies and report to Congress on its progress, as of the publication of this report, this exercise remains uncompleted and no progress report, first due in June of 2003, has been delivered.[26] The current situation has led experts to identify a fundamental lack of coherent organizational systems, structures and chains of commands throughout the public and private biodefense infrastructure.[27]

Effective bioterrorism preparedness requires resources for planning and building detection and response capabilities. However, these resources will ultimately be wasted unless they are accompanied by a clear concept of bioterrorism preparedness and a strategy to achieve it. Clear and reasonable goals for public health and hospital preparedness, measured with quantitative and qualitative capacity and performance indicators, are essential. However, measures used to date have been insufficient. Meaningful standards are largely absent, and states continue to lack standards or guidance how to define preparedness, how to measure it, or how programs will be evaluated.[28,29] The "critical benchmarks" applied to public health and hospital preparedness funding by HHS so far have been minimal in expectations and vague in direction, leaving states with the responsibility to define operational capacities and how to achieve them.[30] The Administration has announced that DHS is now leading the effort to establish preparedness goals.[31] However, no clear methodology or timeline for their delivery has been proposed. Meanwhile, CDC has begun its own new measurement initiative, called the Public Health Preparedness Project, intended to develop indicators to evaluate states' preparedness.[32] But absent the context of a broader bioterrorism plan or a consensus on how measurable outcomes are linked to preparedness goals, it is unlikely that these indicators will have a sufficient real-world

---

[24] James Jay Carafano, "Improving the Federal Response to Catastrophic Bioterrorist Attacks: The Next Steps," *Heritage Foundation Backgrounder No. 1705*, November 15, 2003.

[25] Raymond Decker, General Accounting Office, Testimony before the Committee on Government Reform, Subcommittee on National Security, Emerging Threats, and International Relations, March 3, 2003 (GAO-03-519T).

[26] Sec. 101 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), codified in 42 U.S.C. 300hh.

[27] Chris Strohm, "Agencies Criticized For a Lack of Bioterrorism Strategy," *Government Executive Magazine*, November 14, 2003, http://www.govexec.com/dailyfed/1103/111403c1.htm.

[28] Bernard J. Turnock, *Public Health Preparedness at a Price: Illinois*, (New York, Century Foundation, 2003): 32.

[29] Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction (Gilmore Commission), *Fourth Annual Report to the President and Congress*, December 2002, 54, http://www.rand.org/nsrd/terrpanel/terror4.pdf.

[30] Bernard J. Turnock, *Public Health Preparedness at a Price: Illinois*, (New York: Century Foundation, 2003): 13, 22.

[31] *Budget of the United States Government for Fiscal Year 2005, Analytical Perspectives*, (Washington, D.C.: GPO, 2004): 48.

[32] (a) CDC, *State and Local Preparedness-Progress in Achieving Critical Benchmarks*, presented by Joseph M. Henderson at the meeting of the HHS Secretary's Council on Public Health Preparedness, Washington, D.C., January 22, 2004, http://www.dhhs.gov/asphep/presentation/040122presentationlist.html; (b) Jonathan Radow, "CDC Develops Bioterror Scenarios to Evaluate Preparedness Indicators," *Washington Fax*, November 19, 2003.

basis to accurately measure the many jurisdictions and capabilities needed for preparedness. In addition, financial accountability is generally poor. For example, CDC does not know what states are actually spending on public health or how federal funds are being spent, making it difficult to track activities within states or make comparisons between states.[33]

Finally, in dealing with bioterrorism threats in particular, little consideration has been given to identifying or incorporating bioterrorism threats and vulnerabilities in the allocation of resources.[34] Instead, with the exception of four cities, grants to health agencies and hospitals are distributed in the same amount to all fifty states, with extra adjustments only on the basis of population.[35] As a result, Wyoming has received $15 per capita in bioterrorism preparedness money, while Texas has received $4. The evidence indicates a lack of a coherent strategy for public health preparedness or an working system to achieve it.

SECURITY RECOMMENDATION

The Administration should support the establishment of an Assistant Secretary for Bioterrorism and Public Health Emergencies at DHS. This single official would be responsible for the Department's bioterrorism-related efforts and facilitate coordination and cooperation with other agencies, particularly HHS.[36] In conjunction with HHS, this individual should spearhead the development of a comprehensive, cross-agency, multi-sector, national biodefense plan for preparedness and response and a strategy to achieve this state of readiness. The plan should clearly define the roles and responsibilities of each agency in each sector. Threat and vulnerability assessments need to be conducted and the results incorporated into preparedness and response planning. Such planning should also incorporate aspects unique to bioterrorism, such as forensic analysis. The plan should also seek to supply federal, state, local, and private institutions with the essential capabilities necessary to respond to bioterrorism and other public health emergencies. Those at the federal, state, and local level who are actually involved in the detection and response process must have input into defining these essential capabilities, and preparedness should be defined as their demonstrable achievement and maintenance.

Coherent metrics and goals should be developed so that progress towards preparedness can be achieved and measured. In addition to these metrics, a strategy for reaching these goals should be provided to guide federal, state, and local agencies, Congress, and our private sector partners in setting budgets and priorities. Intentional bioterrorism should not be the only focus. There are likely to be substantial "dual-use" benefits from an improved public health infrastructure that can be derived in numerous emergency situations, as well as day-to-day operations. Plans and standards that maximize these synergies should be developed.

---

[33] Shelly Hearne, President of Trust for America's Health, testimony before the House Committee on Government Reform, February 12, 2004.
[34] Council on Foreign Relations, *Emergency Responders: Drastically Underfunded, Dangerously Unprepared*, June 2003, 30-31.
[35] Holly Harvey, "Fiscal Year 2003 Funding Formula for Bioterrorism Grants," *Congressional Research Service Memorandum*, November, 2003.
[36] James J. Carafano, "Improving the Federal Response to Catastrophic Bioterrorist Attacks: The Next Steps," *Heritage Foundation Backgrounder*, no. 1705, November 13, 2003.

SECURITY GAP: Public Health and Hospital Preparedness Remain Weak.

While further planning and clear standards for preparedness are crucial, it is already evident that the nation's public-health and healthcare-delivery infrastructure, the frontline for bioterrorism detection and response, is in urgent need of better targeted, stronger, and sustained resources. Since 9/11, the Administration and Congress have directed approximately $4 billion towards improving surveillance systems, communications, laboratory capacity, equipment, training, and other aspects of bioterrorism preparedness. However, it is becoming increasingly clear that these funds are poorly targeted and insufficient to meet more than the most modest preparedness goals.

According to Joseph Henderson, Associate Director for Terrorism Preparedness and Response at the CDC, neither "our public health system, nor any public health system in the world, is prepared for a significant bioterror event."[37] The problem, according to Mr. Henderson, is resources. "A billion seems like a lot, but we need more." Experts believe that the severe underfunding of the public health infrastructure over decades has left the system in desperate need of further overhaul,[38] and key services needed for bioterrorism preparedness, such as epidemiological capacity,[39] laboratory capacity,[40] surge capacity,[41] and communication and reporting systems,[42] remain weak. A December 2003 report by the nonpartisan Trust for America's Health found that at the state level, where preparedness programs are reportedly 100 percent financed by federal funds,[43] actual preparedness has only risen modestly and haphazardly.[44] State budget crises, delays in federal grants, and shortages of workers have left only six states with enough laboratory capacity to deal with a public health emergency, and only two with sufficient workers to distribute live-saving medicines from the Strategic National Stockpile. A GAO assessment of federal grants to state and local public health agencies and hospitals found no grantee has met all of the relatively modest "critical benchmarks" required in federal funding guidelines.[45] Local health agencies, those that will actually be involved in a response to bioterror attack, are being overlooked. The vast majority of these jurisdictions receive federal funding through state agencies. But they report delayed and insufficient allocations and poor collaboration with state planners.[46]

---

[37] Caitlin Harrington, "Joe Henderson, CDC's Anti-Terrorism Chief, Gets Paid to Worry," *CQ-Homeland Security*, January 20, 2004.
[38] Committee on Assuring the Health of the Public in the 21st Century, Institute of Medicine, *The Future of the Public's Health in the 21st Century*, (Washinton, D.C.; National Academy Press, 2003).
[39] "Terrorism Preparedness in State Health Departments – United States, 2001-2003," *Morbidity and Mortality Weekly Report*, 52, no. 43 (2003): 1051-1053.
[40] Trust for America's Health, *Public Health Laboratories: Underprepared and Overwhelmed*, June 2003.
[41] Victoria Elliott, "Public Health's Main Fear Over Bioterrorism: Surge Capacity," *American Medical News*, February 24, 2003.
[42] Institute of Medicine, *Microbial Threats to Health: Emergence, Detection, and Response*, (Washington, D.C.: National Academy Press, 2003).
[43] Elin Gursky, *Progress and Peril: Bioterrorism Preparedness Dollars and Health*, (New York: Century Foundation, 2003): 30.
[44] Trust for America's Health, *Ready or Not: Protecting the Public's Health in the Age of Bioterrorism*, December 2003.
[45] GAO, *HHS Bioterrorism Preparedness Programs: States Reported Progress but Fell Short of Program Goals for 2002*, GAO-04-360R, (Washington, D.C.: GAO, February 2004).
[46] (a) United States Conference of Mayors, *Second Mayors' Report to the Nation: Tracking Homeland Security Funds Sent to the 50 State Governments*, January 22, 2004, 19-20, http://www.mayors.org/72ndWinterMeeting/homelandreport_012204.pdf; (b) Elin Gursky, *Progress and Peril: Bioterrorism Preparedness Dollars and Health*, (New York: Century Foundation, 2003): 24-28.

Hospitals and frontline healthcare providers in particular remain underprepared. The GAO reported that no state was able to develop a plan to respond to an epidemic involving at least 500 persons. An independent task force on emergency responders determined that $29.6 billion would be needed over the next five years to achieve adequate hospital preparedness.[47] However, at current fiscal year 2004 funding levels, it would take fifteen years to reach this target. Moreover, the Administration is moving in the opposite direction, requesting four percent and 11 percent reductions in fiscal year 2005 for hospital and public health preparedness funding, respectively. According to the Association of State and Territorial Health Officials, these proposed cuts could jeopardize state's ability to respond to a terror event, outbreak of infectious disease, or other public health threat or emergency.[48] In addition, the separate administration of hospital grants, which is funded through the Health Resources and Services Administration (HRSA) as opposed to CDC, is leading to the isolation of hospitals from other public health emergency planning and readiness.[49]

SECURITY RECOMMENDATION

Funding for public health preparedness should be boosted. There is no evidence that the nation has achieved an adequate state of bioterrorism preparedness. Reducing this funding, as proposed by the Administration for fiscal year 2005, sends the wrong signal to state and local governments, indicating that federal funding to sustain readiness may be withdrawn in the future. This should be avoided as it will undermine our investments in preparedness.

The process for delivering federal funds to state and local jurisdiction needs reform. The Department of Health and Human Services should take greater advantage of its authority to provide more targeted funding directly to local or sub-state regional health agencies. Funding streams should be merged into a single Office of National Public Health Preparedness under the Assistant Secretary for Public Health Emergency Preparedness.

SECURITY GAP: The National Smallpox Vaccination Program Has Failed.

Smallpox is a deadly, disfiguring and contagious disease that could be devastating if used as a weapon by terrorists. While the virus that causes smallpox no longer exists in nature, there is reason to believe it may be accessible to terrorists. The huge Soviet biological weapons program produced tons of weaponized smallpox virus,[50] and its former deputy director, Dr. Ken Alibek, is

---

[47] Council on Foreign Relations, *Emergency Responders: Drastically Underfunded, Dangerously Unprepared*, June, 2003: 35.

[48] Association of State and Territorial Health Officials, "ASTHO Says State Terrorism Preparedness Dollars Critical; Cuts in Proposed FY05 Budget Worrisome," press release, February 3, 2004, http://www.astho.org/templates/display_pub.php?u=JnB1Yl9pZD0xMDEz.

[49] Bernard J. Turnock, *Public Health Preparedness at a Price: Illinois*, (New York: Century Foundation, 2003): 31-32.

[50] (a) Ken Alibek, *Biohazard*: *The Chilling True Story of the Largest Covert Biological Weapons Program in the World*, (New York: Random House Inc., 1999); (b) *The 1971 Smallpox Epidemic in Aralsk, Kazakhstan, and the Soviet Biological Warfare Program*, Jonathan Tucker and Raymond Zilinskas, Eds., Chemical and Biological Weapons Nonproliferation Project, Monterey Institute of International Studies, Occasional Paper No. 9, July 2002.

certain that the virus has escaped from the Soviet program.[51] Dr. D.A. Henderson, the former director of the world smallpox eradication effort, points out that the technology and expertise developed in the Soviet Union during the Cold War is now spread throughout the world.[52]

To confront the threat, in 2002, the Administration directed states to develop smallpox preparedness programs. One of the goals was to vaccinate 500,000 healthcare workers and first responders during 2003 to provide an immune population who could, in turn, care for smallpox victims and administer vaccines to the general public in the event of an attack. Over one year later, a report by the Democratic Members of the Select Committee on Homeland Security has found that only 39,000 personnel have been vaccinated and states nationwide report indefinitely paused vaccination programs, inadequate preparedness, and no real-world means to measure progress or readiness in smallpox preparedness.[53] For example, Nevada reports only 17 vaccinated personnel, while Chicago and New York City have only one vaccinated health worker for every 40,000 people. Forty states report they are unable to vaccinate their populations within ten days of an outbreak. The Administration has contributed to the failure of the smallpox vaccination program through its poor leadership and mismanagement of the program's implementation. As a result, healthcare workers and the public at large have become complacent about the smallpox threat and resistant to vaccination, undermining confidence in the U.S. government and threatening the entire biodefense effort. According to Dr. Tara O' Toole, director of the University of Pittsburgh's Center for Biosecurity, smallpox preparedness has advanced "some small increment," but "essentially our readiness has not improved since 2001."[54]

SECURITY RECOMMENDATION

The Administration should learn from the failures of the vaccination program and restart efforts to achieve smallpox preparedness. A new assessment of the smallpox threat should be made and communicated to state planners, first responders, and the public. Indicators of smallpox preparedness must be developed and integrated into preparedness plans. If these indicators show further vaccinations are required, a reinvigorated, fully funded vaccination effort should be initiated.

Protection Through New Medicines to Fight Pathogens

Truly effective preparedness for bioterrorism requires the tools to detect pathogens, prevent infection, and treat any who fall ill from exposure. According to a 2000 study by the Defense Science Board, at least 57 different countermeasures are needed to defend against 19 of the major bioterrorist agents. Today, only one countermeasure, antibiotic treatment for psittacosis, is

---

[51] Ken Alibek. Testimony before the House Committee on Government Reform, Subcommittee on National Security, Veterans Affairs, and International Relations, October 12, 2001.
[52] David McGlinchey, "Smallpox Immunization Program Stalls," *National Journal*, November 7, 2003.
[53] Democratic Members of the House Select Committee on Homeland Security, *A Biodefense Failure: The National Smallpox Vaccination Program One Year Later*, January 2004, http://www.house.gov/hsc/democrats/pdf/press/040129_ABiodefenseFailureOneYearLater.pdf.
[54] Jonathan Rauch, "Smallpox is Bush's Worst Failure," *National Journal*, November 17, 2003.

effective through multiple disease stages and can be widely distributed.[55] Assessments by the National Institutes of Health have reached the conclusion that we lack many crucial means to defend against likely pathogens.[56] Existing anthrax and smallpox vaccines are too complex or hazardous to protect all population segments, and there are no FDA-approved drugs to treat those who become infected and ill. No vaccine exists for botulinum toxin, pneumonic plague, or tularemia, all considered potential bioterror weapons. Effective drug therapies for viral hemorrhagic fevers are few. In addition, first responders and hospital emergency rooms are without rapid diagnostic tools to detect anthrax, smallpox, plague, botulism, or tularemia.

It is increasingly difficult to separate the dangers of deliberate bioterrorism from those infectious disease threats that arise unintentionally, whether from globalization, environmental change, or evolutionary processes. This year's avian-flu virus in Asia appeared quickly and spread rapidly, putting the entire world on alert.[57] Severe acute respiratory syndrome (SARS), which has claimed more than 800 lives since its discovery, may have arisen from animal storage conditions in China, but spread rapidly overseas.[58] West-Nile virus, which has caused 403 deaths in the U.S. since 2002, and the mega-killer, AIDS, are diseases which traveled to this country from elsewhere. However, resistance of pathogens to existing drugs has become increasingly dangerous. Up to 75 percent of new AIDS patients in the U.S. are resistant to at least one existing antiretroviral therapy.[59] Between 1989 and 2001, some drug-resistant hospital bacterial infections doubled in the U.S.[60] The national and homeland security implications of infectious disease have already been recognized. The National Intelligence Council concluded in 2000 that infectious diseases "will endanger U.S. citizens at home and abroad, threaten U.S. armed forces deployed overseas, and exacerbate social and political instability in key countries and regions in which the United States has significant interests."[61] The nation will continue to face this threat as diseases evolve and new biological threats emerge.

SECURITY GAP: Project Bioshield Is Insufficient and Will Not Produce the Countermeasures We Need.

In proposing Project Bioshield, the Administration has recognized the need to build an arsenal of countermeasures against infectious disease. Today, private pharmaceutical and biotechnology firms are essentially the only entities with the capability to produce safe and effective vaccine, drugs, and medical diagnostics. Thus, the plan's key component, which seeks to engage the

---

[55] Defense Science Board, Department of Defense, "The Projected Evolution of Diagnostics, Vaccines, and Therapeutics Against Major Biogents with Strategic R&D and Supply Actions," *2000 Defense Science Board Summer Study*, (2000).

[56] (a) National Institutes of Allergies and Infectious Diseases, National Institutes of Health, *NIAID Biodefense Research Agenda for CDC Category A Agents*, publication no. 03-5308, February 2002; (b) National Institutes of Allergies and Infectious Diseases, National Institutes of Health, *NIAID Biodefense Research Agenda for CDC Category B and C Priority Pathogens*, publication no. 03-5315, January 2003.

[57] David Brown, "A Horror Script for Health Officials: Bird Flu Poses Global Epidemic Threat," *Washington Post*, January 25, 2004, A19.

[58] World Health Organization. *Summary of Probable SARS Cases with Illness Onset from 1 November 2002 to 31 July 2003*, (revised 26 September 2003), http://www.who.int/csr/sars/country/table2003_09_23/ en/.

[59] R. Grant and others, "Time Trends in Primary HIV-1 Drug Resistance Among Recently Infected Persons, *Journal of the American Medical Association*, 288, no. 2 (2002):181-188.

[60] Centers for Disease Control and Prevention, *MRSA-Methicillin Resistant Staphylococcus Aureas.* http://www.cdc.gov/ncidod/hip/Aresist/mrsa.htm.

[61] National Intelligence Council, *National Intelligence Estimate: The Global Infectious Disease Threat and Its Implications for the United States*, NIE99-17D, (Washington, D.C.: NIC, 2000).

private sector in the development and manufacture of biodefense countermeasures, is a wise first step. However, as currently proposed, Bioshield still does not address critical weaknesses in both the government's and the private sector's ability to deliver biodefense technologies and, as a result, it is unlikely to produce the significant numbers of new medical products that are required for homeland security.

Project Bioshield's central provision, a purchase fund to provide a market for and thus stimulate development of biodefense countermeasures, is probably inadequate. The funding provided in the fiscal year 2004 Homeland Security Appropriations Act totals $5.6 billion through 2014. However, as Rep. Harold Rogers (R-KY), chairman of the House Homeland Security Appropriation Subcommittee said, this amount is "chicken feed to this industry."[62] On average, the development of a new drug or vaccine takes up to ten years and costs $900 million or more.[63] Based on the Defense Science Board's estimate of 56 needed countermeasures, Bioshield would only provide $100 million per new product. This will not be enough to entice private sector firms away from much more lucrative markets in chronic disease treatment, obesity control, or "lifestyle conditions" such as baldness or sexual dysfunction. Medicines for these markets promise returns well above $500 million per product over several years. These market realities have led to industry skepticism about Bioshield and calls for higher guaranteed profits, fewer restrictions on government contracts, and more favorable rules regarding ownership of new discoveries made under the program.[64]

Compounding the reluctance of private sector companies to address this critical public health mission is the rapidly waning capability of pharmaceutical and biotechnology companies to produce the types of medicines needed for biodefense. Because of the potential for higher profits, most are abandoning antimicrobial products in favor of other, more long-term treatments.[65,66] Since 1998, only seven new antibacterials have been approved, and of the 400 drugs likely to be approved in the near future, only five are antibacterial agents.[67] In addition, not a single new class of antibiotics is currently in development. Many generic, essential antibiotics are increasingly in short supply due to decreasing manufacturing capacity.[68] Antiviral drugs are also increasingly suffering from a loss of investment and limited development.[69] The situation with respect to vaccines is much worse. Industrial consolidations, the high cost of research and development (R&D), and persistent difficulties with maintaining profitability, have left the world

---

[62] *Bioshield: Countering the Bioterrorist Threat*, Hearing before the Select Committee on Homeland Security, U.S. House of Representatives, May 15, 2003.

[63] (a) Joseph A. DiMasi, Ronald W. Hansen, and Henry, G. Grabowski. "The Price of Innovation: New Estimates of Drug Development Costs." *Journal of Health Economics*, 22, no. 2 (2003):151-185; (b) Peter Landers, "Cost of Developing a New Drug Increases to About $1.7 Billion" *Wall Street Journal*, December 8, 2003.

[64] Michael Barbaro, "Biodefense Plan Greeted With Caution," *Washington Post*, May 2, 2003, E1.

[65] Roxanne Nelson, "Antibiotic Development Pipeline Runs Dry," *The Lancet*, 362, no. 9397 (2003): 1726-1727.

[66] Tom Clarke, "Drug Companies Snub Antibiotics," *Nature*, 425, no. 6955 (2003): 225.

[67] Infectious Disease Society of America, *Bad Bugs, No Drugs: Defining the Antimicrobial Availability Problem*, Infectious Disease Society of America Backgrounder, November 2003, http://www.idsociety.org/Template.cfm?Section=Policy_and_ Advocacy.

[68] Larry Strausbaugh. Daniel Jernigan, Laura Liedtke, "National Shortages of Antimicrobial Agents," *Clinical Infectious Diseases*, 33, no. 9 (2001):1495-1501.

[69] Institute of Medicine, *Microbial Threats to Health: Emergence, Detection, Response*, (Washington, D.C.: National Academy Press, 2003): 191.

with only five vaccine manufacturers and an anemic capability to develop new vaccines.[70] According to the Institute of Medicine, "our nation and the world face a serious crisis with respect to vaccine development, production, and deployment."[71] Bioshield does not establish sufficient incentives or partnerships with the private sector to overcome these obstacles.

In recognition of the serious barriers to private sector involvement, the Administration has sought to build the federal capacity for countermeasures research and development at the National Institutes of Health (NIH). Since fiscal year 2003, the Administration requested and Congress appropriated more than $3 billion for bioterrorism related R&D at NIH, mostly within the National Institute of Allergies and Infectious Diseases (NIAID). The Administration has requested another $1.7 billion for fiscal year 2005. Project Bioshield also includes proposals that give NIH streamlined procurement, contracting, personnel, and peer-review authorities to enhance the institutes' R&D capabilities. Some of these new powers and resources are to be devoted to basic research activities, a crucial investment and the traditional strength of NIH. The NIAID has also announced that it will devote much of its resources to developing and producing new medicines for biodefense.[72] However, as a recent Institute of Medicine report points out, "NIH has little tradition of product development."[73] Instead, institutes at NIH have traditionally pursued basic research in order to enable private sector development and production of medical technologies. While these activities have provided remarkable advances in biomedical knowledge, NIH has not produced significant numbers of *specific* therapies. In fact, the later stages of clinical testing and product development have generally been left to case-by-case transitions arranged between NIH and the private sector. Of the hundreds of FDA-approved drugs and vaccines, NIH can count only 16 that have directly resulted from advances in its intramural research program.[74] In a separate analysis, NIH found that of a total of 47 FDA-approved "blockbuster" drugs, only four could be linked to government use or ownership rights to patented technologies.[75] Thus, despite recent claims of progress,[76] the history and traditional focus of NIH suggest that without more fundamental reform, the agency will be unlikely to produce the medicines necessary to counter the threat of bioterrorism.

---

[70] Institute of Medicine, *Financing Vaccines in the 21st Century: Assuring Access and Availability*, (Washington, D.C.; National Academy Press, 2003): 107-144.
[71] Institute of Medicine, *Microbial Threats to Health: Emergence, Detection, Response*, (Washington, D.C.: National Academy Press, 2003): 189.
[72] Anthony Fauci, "Biodefense on the Research Agenda," *Nature*, 421, no. 6924 (2003): 787.
[73] Institute of Medicine and National Research Council, *Giving Full Measure to Countermeasures*, (Washington, D.C.: National Academies Press, 2004): 54.
[74] Office of Technology Transfer, NIH, *FDA Approved Therapeutic Drugs and Vaccines Developed with Technologies from the Intramural Research Program at the National Institutes of Health as of April 1, 2003*, http://ott.od.nih.gov/NewPages/therapeutics.pdf.
[75] National Institutes of Health. *A Plan to Ensure Taxpayers' Interests are Protected*, July, 2001, http://www.nih.gov/news/070101wyden.htm#execsum.
[76] National Institutes of Allergies and Infectious Diseases, *NIAID Biodefense Research Agenda for CDC Category A Agents: Progress Report*, August 2003, http://www.niaid.nih.gov/biodefense/research/category_A_Progress_Report.pdf.

SECURITY RECOMMENDATION

The Administration should work with Congress to move beyond Bioshield and develop and implement a strategy that will succeed in producing the safe and effective medical countermeasures we need. Only by working with the private sector and closely following successful medical product development models can government leverage these capabilities to produce the drugs, vaccines, and diagnostics needed to confront bioterrorism and other infectious disease threats. The Administration should establish new, much more innovative mechanisms, such as federally funded venture capital and "virtual" drug development firms, to develop and utilize the best public, private, and academic scientific and technological capabilities to counter microbial threats.

SECURITY GAP: The Threat of Unknown, Resistant or Bioengineered Pathogens Remains Unaddressed.

The Administration has not articulated a vision or developed a plan to confront the new, unexpected infectious disease or bioterrorism threats we will face for years to come. As noted above, the ongoing revolution in the life sciences could propel bioweapons development into a new era of sophistication, enabling the engineering of agents capable of overcoming existing countermeasures.[77] At the same time, our ability to confront certain infectious diseases remains poor. The most recent influenza season was worsened by the failure of current technology to produce sufficient quantities of vaccine for all of those who needed it or to provide the vaccine targeted to combat the actual observed strain.[78] A year after the emergence of SARS, we remain without an effective treatment or vaccine. These kinds of threats can be confronted with broad-spectrum antimicrobial and immunoprotective strategies, as well as the means to rapidly detect, analyze and produce more specific treatments against new, unexpected pathogens. However, only a few, small federal programs exist in these areas, and they remain uncoordinated.[79] In particular, designing and producing new medicines very rapidly - ideally, in a matter of weeks or months under emergency conditions - is a capability that will benefit homeland security as well as other aspects of healthcare. As noted above, the process of moving from "bug-to-drug" can take more than ten years and cost more than $900 million. It should be possible to reduce this timeframe. In fact, the Defense Science Board has outlined a program for meeting this goal by taking advantage of modern proteomics and genomics, better molecular targeting technologies, advances in high-throughput techniques, and computational optimization of drug candidates [80] So far, these recommendations have not resulted in specific policy proposals.

---

[77] Bradley A. Smith, Thomas V. Inglesby, and Tara O'Toole, "Biodefense R&D: Anticipating Future Threats, Establishing a Strategic Environment," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 1, no. 3 (2003): 193-202.

[78] Lawrence Altman, 'The Big Bad Flu, or Just the Usual," *New York Times*, December 14, 2003, A43.

[79] For example, see Defense Advanced Research Projects Agency, Department of Defense, *Pathogen Countermeasures*, http://www.darpa.mil/dso/thrust/biosci/upathcm.htm.

[80] Defense Science Board, Department of Defense, *2001 Summer Study on Defense Science and Technology*, (May 2002): 108-115, http://www.acq.osd.mil/dsb/sandt.pdf.

SECURITY RECOMMENDATION

The Administration should explore the feasibility of a broad multi-agency effort to dramatically improve the "bug-to-drug" response time. Compressing the timeline for drug and vaccine development is a critical element of facing future bioterrorist and infectious disease threats. Achieving this transformation will not be easy, and it will require the participation and cooperation of many federal agencies and the private sector. It is an endeavor worthy of American ingenuity and leadership, and it will be as challenging as it will be beneficial, for biodefense, public health, and the economy.